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**IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF UTAH, CENTRAL DIVISION**

<p>MARK L. SHURTLEFF, ATTORNEY GENERAL OF THE STATE OF UTAH, <i>ex rel.</i> THE STATE OF UTAH,</p> <p style="text-align: center;">Plaintiff,</p> <p>v.</p> <p>JANSSEN ORTHO LLC, ORTHO-MCNEIL- JANSSEN PHARMACEUTICALS, INC., and ASTRAZENECA PHARMACEUTICALS LP,</p> <p style="text-align: center;">Defendants.</p>	<p>Case No. 2:10-CV-00519-BSJ</p> <p style="text-align: center;"><b>PLAINTIFF’S REPLY TO DEFENDANT ASTRAENECA PHARMACEUTICALS LP’S OPPOSITION TO PLAINTIFF’S MOTION TO REMAND FOR LACK OF SUBJECT MATTER JURISDICTION</b></p>
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Introduction

The Court and the parties should not misunderstand the plaintiff’s position on removal to Federal Court. If this were merely a change of venue or the assignment of a new judge, Plaintiff would have no objection. Under such circumstances, Plaintiff would be perfectly happy to have this matter heard in this Court.

Unfortunately for Defendants, the issue here, however, is federal jurisdiction. Because jurisdiction cannot be created by the parties, Plaintiff must object to Defendants’ improvident removal. If it does not object, it does so at its peril.

This has been true for over a century. An illustrative case is *Mansfield Coldwater & Lake Michigan Ry. V. Swan*, 111 U.S. 379 (1884). There, the plaintiff brought suit in Ohio state court. The defendants removed to federal court, alleging diversity jurisdiction. The plaintiff resisted federal jurisdiction, but the trial court overruled the objection. The plaintiff recovered sizable verdicts and judgments against the defendants. On appeal to the Supreme Court, the

defendants argued that the verdicts and judgments should be vacated because the trial court lacked jurisdiction. Even though the decision worked a hardship on the plaintiff who was without fault, the Supreme Court dismissed the action and vacated the judgment because it appeared that the trial court wrongfully decided the jurisdiction question. *Id.* at 381—82.

[T]he rule [that lack of federal jurisdiction requires remand], springing from the nature and limits of the judicial power of the United States, is inflexible and without exception which requires this court, of its own motion, to deny its own jurisdiction, and, in the exercise of its appellate power, that of all other courts of the United States, in all cases where such jurisdiction does not affirmatively appear in the record on which, in the exercise of that power, is called to act.

*Id.* at 382. Here, should Plaintiff prevail at trial and obtain a judgment in this Court, Plaintiff would have the burden of showing the existence of federal jurisdiction—a burden Plaintiff cannot carry.

This is why the courts, particularly those in the Tenth Circuit, resolve all doubts about federal jurisdiction in favor of remand. “Removal statutes are to be strictly construed . . . and all doubts are to be resolved against removal.” *Fajen v. Found. Reserve Ins. Co.*, 683 F.2d 331, 333 (10th Cir. 1982) (internal citations omitted). The remand statutes must “be strictly construed . . . . Any doubts about the validity of a removal are resolved in favor [of] remand.” *Jackman v. Select Specialty Hospital-Kansas City, Inc.*, 2009 WL 3672509, \*2 (D. Kan. 2009). There is a presumption against removal jurisdiction and removal statutes are strictly construed with any doubts resolved in favor of remand. *Laughlin v. Kmart Corp.*, 50 F.3d 871, 873 (10th Cir. 1995).

In other words, unless federal jurisdiction appears on the face of the complaint, where here it does not, the Tenth Circuit would require this Court to grant the motion for remand to state court. *Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation Trust for S. Cal.*, 463 U.S. 1, 17-18 (1983). This case, therefore, must be remanded.

## Argument

### **I. The State's Cause of Action does not require interpretation of Federal Medicaid Law.**

The Defendant's Opposition papers recite the term "medically accepted" as if it were some mantra which would ward off state jurisdiction. "Medically accepted" is not a mysterious term. It simply means the drug's approval for FDA use or uses specified in three recognized compendia. Defendants argue that if their drug were "medically accepted" the Plaintiff would have no choice but to pay for it. The Defendants thereafter confuse the duty to pay with the absence of the Plaintiff's right to collect damages when they misrepresent the safety and efficacy of their drug. Therefore, they claim that a federal interpretation of "medically accepted" is the controlling factor because the Plaintiff has to pay for "medically accepted drugs."

It is clear that these defendants file this motion in every jurisdiction because they have not recognized that this case is brought under Utah specific law. A failure of a drug to be "medically accepted" may be proof of a Utah false claim but is not dispositive. The Defendant's interpretation of federal law may be dispositive in other states. For example in the recent case of *Louisiana v. Merck*, 2010 WL 264951, the state was limited to a particular Louisiana cause of action known as "redhibition." Louisiana was required to prove that the Louisiana Department of Health would have done something other than continue to pay for the pharmaceutical "Vioxx" had it known the truth. This is not the same as a Utah cause of action for making a false claim concerning the safety and efficacy of the drug. These defendants' argument that Utah had no choice but to pay for their drug is irrelevant to the Utah provisions requiring full and complete restitution for damages resulting from Defendants' drugs.

Other States' laws provide similar results. For example, the State of Alaska brought suit against Eli Lilly under the Alaska Unfair Trade Practices and Consumer Protection Act for

Lilly's misrepresentations concerning its atypical antipsychotic, Zyprexa.. Alaska only required proof of misrepresentation to the State Medicaid population and their providers. The term "medically accepted" had nothing to do with either the State's proof or the manufacturer's defense. While "medically accepted" might have reference in Louisiana, it had none in Alaska and it likewise has no application here.

Here, Utah brings its action under the Utah False Claims Act, Utah Code Ann. §26-20-1 *et seq.* Utah's allegation is that these defendants caused to be presented to the Utah Health Department a claim for medical benefits which was "wholly or partially false, fictitious or fraudulent." Utah Code Ann. §26-20-7 (1). The scienter requirement is "reckless disregard of the truth or falsity of the information" and does not require a specific intent to defraud." Utah Code Ann. §26-20-9.5(1) (a). Liability is imposed for presenting a false claim whether the State paid for it or not. It is evident that claims for these drugs have been presented and that the State has paid for them. The question is the "falsity" of the claims presented to the State and the restitution to be paid.

"False representation" means a wholly or partially untrue statement or representation. Utah Code Ann. §26-20-2(3). "False Representation" as set forth in the Utah False Claims Act does not mean a drug that is not "medically accepted." It means that the drug was not what it was represented to be. Here, the allegations are that the defendants misrepresented the safety and efficacy of their drugs. Some of those "false representations" would have been for uses that were "medically accepted" because as alleged the Defendants' drugs cause hyperglycemia, weight gain and diabetes. The State had to pay for the Medicaid recipients who suffered those conditions because of the defendants' drugs. Plaintiff is entitled to "full and complete restitution" of all damages the Plaintiff suffers as a result of a false claim. Utah Code Ann. §26-20-9.5(2)(a).

It does not matter whether the state suffered those damages as a result of a “medically accepted” or non-medically accepted use. The State’s cause of action is the same in either instance. The definition (of which there is really no dispute) makes no difference to either the Plaintiff’s proof or the defendant’s defense. And, to be sure, an affirmative defense is insufficient to confer federal jurisdiction. *Utah v. Lilly*, 509 F.Supp.2d 1016, 1022 (D. Utah 2007).

## **II. The Supreme Court has Provided Guidance on the Question of Remand**

There is no controlling authority in this Circuit as to federal jurisdiction in Attorney General Medicaid actions. As both parties have demonstrated, there are a number of district court opinions on this issue throughout the nation. The Court may be tempted to weigh the reasoning and rationale of these decisions to make its judgment. This would be a mistake. The United States Supreme Court in three decisions has given ample authority to decide this matter.

In *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804 (1986), the Court found that there was no federal jurisdiction is a state tort claim resting in part upon an allegation that the defendant drug company had violated a federal drug branding law. There, the Court noted that Congress had not provided a federal cause of action for such violations. *See generally id.*

The case upon which Defendants principally rely is *Grable & Sons Metal Products, Inc. v. Darue Engineering and Manufacturing*, 545 U.S. 308(2005). There, the defendants sought removal from a state court quiet title action in which the sole question was the legal effect of an I.R.S. foreclosure. The Court held that such removal was proper and necessary to the exercise of federal jurisdictional powers. It held that the lack of a federal remedy was not of itself fatal to removal. More importantly, *Grable* did not overrule *Merrell Dow*, “Accordingly, *Merrell Dow* should be read in its entirety as treating the absence of a federal private right of action as

evidence relevant to, but no dispositive of, the ‘sensitive judgments about congressional intent’ that 1331 requires.” *Id.* at 318. “The absence of any federal cause of action . . . [was] worth some consideration in the assessment of substantiality.” *Id.* at 318. The primary importance, however, was the combination of no cause of action and no federal preemption. *See id.* at 318. This was an important clue as to Congressional intent as to the exercise of federal jurisdiction. *See id.* at 318. The missing cause of action was not a missing federal door key, which is always required. *See id.* at 318. It was a “missing welcome mat, required in the circumstance, when exercising federal jurisdiction over a state misbranding action which would have attracted a horde of original filings and removal cases raising other state claims with embedded federal issues.” 545 U.S. 308 at 318. .

The Court made clear that *Grable* is the anomaly and not the rule. In *Empire Healthchoice Assurance, Inc. v. McVeigh*, 547 U.S. 677(2006), the Court considered federal jurisdiction in the context of a suit by a health insurance carrier for federal employees seeking reimbursement of benefits the enrollee had recovered in a state court action. The Court described *Grable* jurisdiction as a “special and small category.” 547 U.S. at 699. *Grable* presented a “nearly pure question of law.” *Id.* at 681. “In sum, *Grable* emphasized that it takes more than a federal element “to open the ‘arising under’ door.”” 547 U.S. at 701.

The question, therefore, is if this case comes within the small and special category set forth in *Grable*. It is clear that this case does not involve a pure question of federal law. Indeed, federal Medicaid law is subordinate to the interpretation of state Medicaid regulations and, more importantly, the Utah False Claim Act. A decision by a federal court will not decide for all time the issues of false claims as did the legal decision in *Grable*. Further, there is no dispute that Congress told the States to pursue these Medicaid actions and then did not give them a federal

cause of action to do so. There is no *Grable* “welcome mat” for this case. The instruction to bring the action without creating a federal cause of action is clear indication that Congress knew and intended these actions to be brought by the States in state court under state statute or common law. The lack of Congressional intent as demonstrated by this lack of a federal cause of action is dispositive.

Judge Stewart of this District reached the same conclusion in *The State of Utah v. Eli Lilly, et al.*, 509 F.Supp.2d 1016 (2007). The court found that complaint, almost identical to this complaint, did not raise a substantial federal issue. The Court cited *Merrell Dow* and *Grable*. *Id.* at 1022. “[T]he mere presence of a federal standard embedded in a state law cause of action is not sufficient to warrant federal subject matter jurisdiction where there is no federal remedy for a violation of the federal statute.” *Id.* at 1022.

In *Utah v. Eli Lilly*, the Court held that Congress had no intent that the federal courts exercise jurisdiction over Medicaid statutes. The district court emphasized the Court’s language from *Empire*:

“[F]ederal courts should await a clear signal from Congress before treating such ancillary claims as ‘arising under’ the laws of the United States.” There is no meaningful indication that Congress intended to confer federal jurisdiction over state law causes of action implicating the federal statutes involved here, namely, the FDCA and Title XIX of the Social Security Act . . . which is the federal legislation establishing the Medicaid program.

509 F.Supp. 2d at 1023. There has been no change in controlling precedent after Judge Stewart’s decision. Judge Stewart’s decision was well-grounded in Supreme Court authority. There is no reason to reach a different conclusion here.

It is admitted that Utah Medicaid law adopts a term used in Federal Medicaid law. The Defendants argue that this adoption of a federal term implicates federal jurisdiction. Their argument is incorrect because it does not reflect Supreme Court authority. *Merrell Dow* was a



state law cause of action reflecting federal statutory standards. The Supreme Court found that the adoption of federal law and standards in a state law cause of action did not open the door to federal jurisdiction. That finding was not disturbed by *Grable* or *Empire*.

Plaintiff's complaint is clearly based upon state statutes and common law. The fact that it refers to federal standards makes it exactly the same situation as found in *Merrell*. The Court has never indicated that a reference to a federal standard in a state cause of action is evidence of Congressional intent to confer federal jurisdiction.

It is telling that Defendants cite no congressional authority showing any intent to confer federal jurisdiction through a reference to a term found in federal Medicaid law. Indeed, when the federal Medicaid scheme is viewed in its entirety, such a requirement would conflict with Congress' clear indication that the Attorneys General were to bring Medicaid reimbursement suits under State law.

### **III. Concerns of Federalism**

All of the Supreme Court cases were concerned with the importance of maintaining a balance between the labors of state and federal courts. Judge Stewart also addressed this matter in *Eli Lilly*. He found that an exercise of federal jurisdiction would upset the congressionally-approved balance of federal and state judicial responsibilities. There was no federal cause of action. As indicated by Judge Stewart in *Eli Lilly*, "the Supreme Court itself has stated that 'considerations of comity make us reluctant to snatch cases which a State has brought from the courts of that State, unless some clear rule demands it.'" *Id.* at 1025 (citing *Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation*, 463 U.S. 1, 22, n.22 (1983)).

This case, brought by the Attorney General on behalf of the State, involves most particularly the interpretation of the Utah False Claims Act as applied to Utah Medicaid. Utah

Medicaid is administered by the Utah Department of Health. This case is directly concerned with how the State of Utah provides pharmaceutical benefits to the indigent. It is centered in state agencies and interprets state law. There is no clear rule that requires a federal court to snatch this state action from the Courts of Utah. If Congress or the Supreme Court intended this result, they would have provided a clear indication of intent. The lack of clear intent is demonstrated most clearly by Defendants' voluminous pleadings.

#### **IV. Federal Preemption.**

The argument that the Federal Government has totally preempted actions relating to the Federal Drug and Cosmetic Act (FDCA) was resolved by the Court in *Wyeth v. Levine*, 129 S.Ct. 1187, 1193-1204 (March 4, 2009).

#### **Conclusion**

Federal Jurisdiction must appear on the face of the Complaint. If it does not, this Court may not hear the matter. Affirmative defenses do not raise federal issues. Improvident removal exposes both parties to the risk of later remand. Therefore, all doubts are to be exercised in favor of remand.

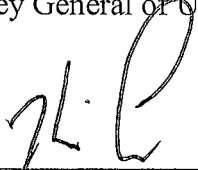
The Supreme Court has clearly indicated that the lack of congressional intent is dispositive in a question of federal jurisdiction. Here, Congress told the states to bring these actions but provided no federal cause of action. There is before the court no other expression of congressional intent.

Snatching this case from Utah state court will upset the balance of federalism. The case is most particularly involved with Utah statutes and the administration of a state program. The fact that there is federal involvement in the FDCA and Medicaid is no reason to preclude Utah from enforcing its law in its courts.

The Motion for Remand should be granted.

DATED this 27<sup>th</sup> day of July, 2010.

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**CERTIFICATE OF SERVICE**

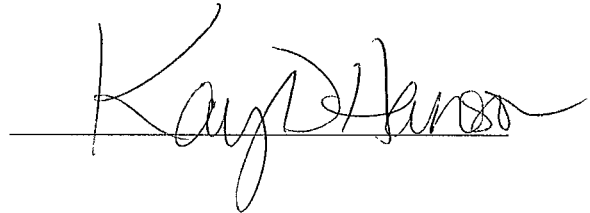
I hereby certify that on the 27<sup>th</sup> day of July, 2010 a true and correct copy of

**PLAINTIFF'S REPLY TO DEFENDANT ASTRAZENECA'S OPPOSITION TO  
PLAINTIFF'S MOTION TO REMAND FOR LACK OF SUBJECT MATTER**

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A handwritten signature in cursive script, appearing to read "Kay D. Hatch", is written over a horizontal line.